

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

STANLEY EBERT,

Plaintiff,

v.

MERCK, SHARP & DOHME, CORP.,
BARR PHARMACEUTICALS, INC.,
BARR LABORATORIES, INC.,
COBALT LABORATORIES, INC. and
AUROBINDO PHARMA U.S.A., INC.

MASTER FILE: 1:06-md-1789-JFK

In Re: Civil Action No.:

Defendants.

COMPLAINT

COMES NOW the Plaintiff, STANLEY EBERT, for causes of action against MERCK, SHARP & DOHME, CORP., formerly known as MERCK & Co., Inc., (hereinafter "Defendant" and/or "MERCK"); BARR PHARMACEUTICALS, INC., BARR LABORATORIES INC., COBALT LABORATORIES, INC., and AUROBINDO PHARMA U.S.A., INC.-hereinafter collectively known as "GENERIC DEFENDANTS"), allege as follows:

I. JURISDICTION AND VENUE

1. This Court has jurisdiction pursuant to 28 U.S.C. §§1332, as complete diversity exists between Plaintiff and at least one Defendant and the amount in controversy, exclusive of interest and costs, exceeds \$75,000.

2. Venue is proper within this district pursuant to Case Management Order No. 3, filed November 1, 2006, signed by John F. Keenan, allowing Fosamax-related cases to be filed directly in the Southern District of New York.

II. PARTIES

3. Plaintiff STANLEY EBERT at all relevant times was a resident of the State of California, and used FOSAMAX and/or ALENDRONATE for the treatment and/or prevention of osteoporosis or osteopenia.

4. Defendant MERCK is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business in New Jersey. The Defendant's registered office is at 820 Bear Tavern Road, City of West Trenton, Mercer County, New Jersey.

5. Defendant, BARR PHARMACEUTICALS INC., is a corporation organized and existing under the laws of the State of Delaware. The Defendant's principal place of business is located at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey, 07677. Defendant is owned by TEVA PHARMACEUTICAL INDUSTRIES LTD.

6. Defendant, BARR LABORATORIES, INC., is a corporation organized and existing under the laws of the State of Delaware. The Defendant's principal place of business is located at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey, 07677. Defendant

was a wholly owned subsidiary of Barr Pharmaceuticals, Inc.

7. COBALT LABORATORIES, INC., a subsidiary of Watson Pharmaceuticals, Inc., is a corporation organized and existing under the State of Delaware. The Defendant's principal place of business is located at 24840 Tamiami Trail, Building B, Suite 1, Bonita Springs, FL 34134. The Registered Agent is located at The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801.

8. AUROBINDO PHARMA U.S.A., INC., is a corporation organized and existing under the State of Delaware. The Defendant's principal place of business is located at 2400 US Highway 130, Dayton, NJ 08810.

9. At all relevant times herein, MERCK was authorized to and regularly conducted business in the State of New York and continues to do so.

10. The GENERIC DEFENDANTS are: BARR PHARMACEUTICALS, INC., BARR LABORATORIES INC., COBALT LABORATORIES, INC. and AUROBINDO PHARMA U.S.A., INC.

11. At all relevant times herein, GENERIC DEFENDANTS were authorized to and regularly conducted business in the State of New York and continue to do so.

12. At all relevant times, Defendant MERCK, through its agents, servants, employees and apparent agents was the designer, manufacturer, labeler, promoter, marketer, distributor, supplier and seller of FOSAMAX, FOSAMAX PLUS D and ALENDRONATE SODIUM (hereinafter referred to collectively as FOSAMAX only as to MERCK), a bisphosphonate drug used primarily to prevent, mitigate or reverse the effects of

osteoporosis and Paget's Disease.

13. At all relevant times, GENERIC DEFENDANTS, by and through their agents, servants, employees and apparent agents, were the manufacturers, labelers, promoters, marketers, distributors, suppliers and/or sellers of ALENDRONATE SODIUM, a bisphosphonate drug used primarily to prevent, mitigate or reverse the effects of osteoporosis and Paget's Disease.

14. GENERIC DEFENDANTS, either directly or through their agents, apparent agents, servants or employees at all relevant times sold and/or distributed ALENDRONATE SODIUM in the State of New York.

15. Beginning in or around February 2008, GENERIC DEFENDANTS, by and through their agents, servants, employees and apparent agents, were the manufacturers, labelers, promoters, marketers, distributors, suppliers and/or sellers of ALENDRONATE SODIUM, a generic drug for FOSAMAX.

16. Defendant MERCK derives substantial revenue from pharmaceutical products used, sold, marketed, distributed and/or consumed in the State of New York and expected, or should have expected, that its business activities could or would have consequences within the State of New York.

17. GENERIC DEFENDANTS derive substantial revenue from pharmaceutical products used, sold, marketed, distributed and/or consumed in the State of New York and expected, or should have expected, that its business activities could or would have consequences within the State of New York.

18. Defendant MERCK placed FOSAMAX into the stream of worldwide commerce and interstate commerce in the United States and in the State of New York. It did so without adequate testing and with inadequate or no warning that the drug carried with it a risk of causing osteonecrosis of the jaw and other serious jaw injuries. It also did so without adequate instructions regarding the appropriate duration of use for FOSAMAX.

19. GENERIC DEFENDANTS placed ALENDRONATE SODIUM into the stream of worldwide commerce and interstate commerce in the United States and the State of New York. It did so with inadequate or no warning that the drug carried with it a risk of causing osteonecrosis of the jaw and other serious jaw injuries. It also did so without adequate instructions regarding the appropriate duration of use for ALENDRONATE SODIUM.

20. STANLEY EBERT, at all times relevant, resided in Fresno, California and took FOSAMAX, manufactured and sold by MERCK and/or, sometime after February 2008, ALENDRONATE SODIUM, sold by one or more of GENERIC DEFENDANTS. STANLEY EBERT suffered and may continue to suffer severe and permanent personal injuries, including but not limited to, osteonecrosis of the jaw and other diagnoses of irreversible damage to the jaw as a result of taking FOSAMAX and/or ALENDRONATE SODIUM.

III. SUMMARY OF THE CASE

21. Defendant MERCK, either directly or through its agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed and sold

FOSAMAX for the treatment of osteoporosis, Paget's Disease, and other off-label uses.

22. Defendant MERCK concealed its knowledge of FOSAMAX's unreasonably dangerous risks from Plaintiff STANLEY EBERT, his physicians, other consumers, and the medical community.

23. Defendant MERCK failed to conduct adequate and sufficient post-marketing surveillance of FOSAMAX after it began marketing, advertising, distributing, and selling the drug.

24. GENERIC DEFENDANTS, either directly or through its agents, apparent agents, servants or employees marketed, distributed and sold ALENDRONATE for the treatment of osteoporosis, Paget's Disease, and other off-label uses.

25. GENERIC DEFENDANTS failed to conduct adequate and sufficient post-marketing surveillance of ALENDRONATE after it began distributing and selling the drug.

26. The FOSAMAX manufactured, advertised, distributed and sold was defective in that the risks associated with its use outweighed any benefits conferred to the patients, including Plaintiff, to whom it was prescribed, and safer alternative therapies were available to consumers such as Plaintiff.

27. As a result of Defendant MERCK's actions and inaction, as well as the defective nature of FOSAMAX, persons who were prescribed and ingested FOSAMAX, including Plaintiff STANLEY EBERT, have suffered and may continue to suffer severe and permanent personal injuries, including but not limited to, osteonecrosis of the jaw and other diagnoses of irreversible damage to the jaw. Plaintiff accordingly seeks

compensatory damages.

28. The ALENDRONATE manufactured, advertised, distributed and sold by GENERIC DEFENDANTS was defective in that the risks associated with its use outweighed any benefits conferred to the patients, including Plaintiff, to whom it was prescribed, and safer alternative therapies were available to consumers such as Plaintiff.

29. As a result of GENERIC DEFENDANTS' actions and inaction, as well as the defective nature of ALENDRONATE, persons who were prescribed and ingested ALENDRONATE, including Plaintiff STANLEY EBERT, have suffered and may continue to suffer severe and permanent personal injuries, including but not limited to, osteonecrosis of the jaw and other diagnoses of irreversible damage to the jaw. Plaintiff accordingly seeks compensatory damages.

FACTUAL BACKGROUND

30. At all relevant times Defendant MERCK was responsible for, or involved in, designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX, and designing and manufacturing the ALENDRONATE sold by GENERIC DEFENDANTS under the brand name FOSAMAX.

31. At all relevant times GENERIC DEFENDANTS was responsible for, or involved in, marketing, distributing, and selling ALENDRONATE.

32. In September 1995, MERCK received FDA approval of its drug FOSAMAX.

33. FOSAMAX falls within a class of drugs known as bisphosphonates.

Bisphosphonates are used for treating bone conditions such as osteoporosis and Paget's disease. Other drugs within this class such as Aredia and Zometa are also used as chemotherapy and as adjunct chemotherapy but are not indicated for use in non-cancerous conditions such as osteoporosis.

34. There are two classes of bisphosphonates: the N-containing (nitrogenous) and non-N-containing (non-nitrogenous) bisphosphonates. The nitrogenous bisphosphonates include the following: pamidronate (Aredia); ibandronate (Boniva); risedronate (FOSAMAX); and alendronate (Fosamax). The non-nitrogenous bisphosphonates include the following: etridonate (Didronel); clodronate (Bonefos and Loron); and tiludronate (Skelid). Alendronate, like the others, contains a nitrogen atom, whereas etridonate, clodronate, and tiludronate do not. The PDR for Fosamax confirms that the molecule contains a nitrogen atom.

35. FOSAMAX works by suppressing the process known as bone resorption. Bone resorption is the process of removing old and unhealthy bone cells, which then indirectly initiates the process of producing new bone cells.

36. Throughout the 1990s and 2000s, medical articles and studies appeared reporting the frequent and common occurrence of osteonecrosis of the jaw within the nitrogenous bisphosphonates used for chemotherapy. As with its reported and acknowledged side effects concerning irritation, erosion, and inflammation of the upper gastrointestinal tract, MERCK knew or should have know that FOSAMAX, as a nitrogenous bisphosphonate, shared a similar adverse event profiles to the other drugs within this specific subclass of

bisphosphonates (i.e., those containing nitrogen).

37. Defendant MERCK knew and/or should have known that bisphosphonates, including FOSAMAX, suppress bone turnover and could therefore, compromise the ability of the jaw bone to heal. As a result, a minor injury or disease can turn into a non-healing wound that in turn can progress to widespread necrosis (bone death) and osteomyelitis (inflammation of bone marrow).

38. Likewise, GENERIC DEFENDANTS knew and/or should have known that ALENDRONATE suppresses bone turnover and could compromise the ability of the jaw bone to heal, which could in turn lead to widespread necrosis and osteomyelitis.

39. Dentists are now being advised by state dental associations to refrain from using any invasive procedure (such as drilling a cavity) for any patient on FOSAMAX or ALENDRONATE.

40. Once the osteonecrosis begins and becomes symptomatic, it is very difficult to treat and is not reversible.

41. Shortly after Defendant MERCK began selling FOSAMAX, reports of osteonecrosis of the jaw and other dental complications among users began surfacing, indicating that FOSAMAX shared the class effects of the other nitrogenous bisphosphonates. Despite this knowledge, MERCK failed to implement further study of the risk of osteonecrosis of the jaw relative to FOSAMAX. Rather than evaluating and verifying the safety of FOSAMAX with respect to osteonecrosis of the jaw, MERCK proposed further uses of FOSAMAX, such as FOSAMAX-D, and sought to extend the exclusivity period of

FOSAMAX through 2018.

42. Osteonecrosis of the jaw is a serious medical event and can result in severe disability and death.

43. Since FOSAMAX was released, the FDA has received a number of reports osteonecrosis of the jaw among users of FOSAMAX.

44. On August 25, 2004, the FDA posted its ODS (Office of Drug Safety) Postmarketing Safety Review on bisphosphonates - - specifically pamidronate (Aredia), zoledronic acid (Zometa), risedronate (FOSAMAX), and alendronate (FOSAMAX). This was an epidemiologic review of the FDA adverse events database conducted by the FDA's Division of Drug Risk Evaluation.

45. As a result of the FDA Review, the FDA observed that the risk of osteonecrosis of the jaw was not confined to bisphosphonates used for chemotherapy. The FDA's review indicated that the osteonecrosis of the jaw was a class effect, which specifically extended to the oral bisphosphonate, FOSAMAX.

46. Rather than warn patients, and despite MERCK's knowledge of an increased risk of osteonecrosis of the jaw in patients using FOSAMAX, MERCK continued to defend FOSAMAX and minimize unfavorable findings.

47. FOSAMAX was one of MERCK's top selling drugs. Averaging more than \$3 billion a year in sales until the expiration of FOSAMAX's patent in February 2008.

48. Commercial retail pharmacies typically fill prescriptions with generic versions of name brand drugs when a generic version is available. All 50 states have some form of

“drug substitution law”, which requires or permits a pharmacist to fill a prescription for a particular drug, whether identified by brand name (such as “Fosamax”) or by generic name (such as “Alendronate”), with a cheaper generic version of the drug.

49. Physicians are aware that generic drugs will be substituted for name brand drug prescriptions they write.

50. All wholesale shipments of prescription drug products, and all samples of such products, are accompanied by “package inserts”, which contain information about the product, including its active and inactive ingredients, pharmacokinetics, chemistry, warnings, and side effects. The verbatim content of the package insert, for a name brand prescription drug product, is typically published, as a so-called “monograph” for the product, in the Physician’s Desk Reference (PDR), an annual compilation of such monographs, supplemented periodically. A monograph for any prescription drug product may be published in the PDR at the instance of the manufacturer, upon payment of a fee to the publisher.

51. Merck is aware that physicians routinely rely on the package insert and PDR monograph for Fosamax in instances when the physician is also aware that substitution with Alendronate is certain to occur by the patient’s pharmacist.

52. A physician’s reliance on the information concerning the properties and effects contained in the package insert (or PDR monograph) for Fosamax, is foreseeable and reasonable. It is equally foreseeable and reasonable that physicians will rely on the Fosamax package insert (or PDR monograph) for information as to the properties and

effects of therapeutically equivalent Alendronate.

53. Generic Defendants adopted, in substance, the text of the “package insert” for Fosamax, as revised from time to time by Merck, as the package insert for Alendronate, modified only to reflect therapeutically non-relevant differences among products, such as color, shape, inactive ingredients, and source of manufacture, as required by federal law.

54. Generic Defendants relied upon Merck to communicate to physicians adequate information concerning the appropriate length of use and risks entailed in the use of Alendronate products, including both Fosamax and the bioequivalent and therapeutically equivalent generic Alendronate, and Generic Defendants adopted, as applicable to its own Alendronate product, such information as was disseminated about Fosamax and/or Alendronate by Merck.

55. The package inserts for Alendronate, and the PDR monograph for Fosamax, contained false and/or misleading statements and omitted information material to the foreseeable and ordinary contemplated uses of Alendronate and Fosamax. False and/or misleading information was also provided by Merck, and adopted by Generic Defendants, by way of Merck’s advertising, marketing materials, detail persons, seminars presentations, publications, notice letters, and regulatory submission.

56. In prescribing Fosamax and/or Alendronate for Plaintiff, Plaintiff’s physicians reasonably relied upon the information published in the package inserts and/or the PDR and/or otherwise disseminated by Merck through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and

regulatory submissions, and were not aware of information different from or contrary to the inaccurate, misleading, materially incomplete, false, and/or otherwise inadequate information thus disseminated.

57. Plaintiff's injuries occurred as a foreseeable and proximate result of Merck's dissemination to physicians, including Plaintiff's physician, inaccurate, misleading, materially incomplete, false, and otherwise inadequate information concerning the potential adverse effects of prolonged Fosamax and/or Alendronate use including, but not limited to, osteonecrosis of the jaw.

58. With WATSON, MERCK continued to profit from the sale of ALENDRONATE under the authorized generic agreement with WATSON, whereby MERCK manufactured ALENDRONATE and WATSON sold it under the brand name FOSAMAX.

59. Consumers, including Plaintiff STANLEY EBERT, who have used FOSAMAX for the treatment or prevention of osteoporosis, Paget's Disease and/or other off-label uses, have several alternative safer products available to treat their conditions.

60. Defendants MERCK and GENERIC DEFENDANTS knew or should have known of the significant risk of dental and oral complications caused by the ingestion of FOSAMAX, but Defendants did not adequately and sufficiently warn consumers, including Plaintiff STANLEY EBERT, or the medical community, of such risks.

61. As a direct result, Plaintiff STANLEY EBERT was prescribed FOSAMAX and/or ALENDRONATE and has been permanently and severely injured, having suffered serious consequences from the ingestion of FOSAMAX and/or ALENDRONATE.

Plaintiff STANLEY EBERT requires and will in the future require ongoing medical care and treatment.

62. Plaintiff STANLEY EBERT has suffered from mental anguish from the knowledge that she will have life-long complications as a result of the injuries Plaintiff sustained from the use of FOSAMAX.

63. Plaintiff STANLEY EBERT was prescribed and began taking FOSAMAX for the treatment and/or prevention of osteoporosis or osteopenia.

64. Plaintiff used ALENDRONATE sold by GENERIC DEFENDANTS for the treatment and/or prevention of osteoporosis or osteopenia.

65. Plaintiff used FOSAMAX, which had been provided to him in a condition that was substantially the same as the condition in which it was manufactured and sold, as prescribed and in a foreseeable manner.

66. Plaintiff used ALENDRONATE, which had been provided to him in a condition that was substantially the same as the condition in which it was manufactured and sold, as prescribed and in a foreseeable manner.

67. As a direct and proximate result of using FOSAMAX and/or ALENDRONATE, Plaintiff suffered a severe injury to his jaw.

68. Plaintiff, as a direct and proximate result of using FOSAMAX and/or ALENDRONATE, suffered severe mental and physical pain and suffering and has sustained permanent injuries and emotional distress.

69. Plaintiff would not have used FOSAMAX and/or ALENDRONATE had Defendants

MERCK and GENERIC DEFENDANTS properly disclosed the risks associated with the drug. Alternatively, Plaintiff would have known the precursor events of osteonecrosis of the jaw and would have been able to avoid the clinical manifestation of the symptoms as they currently exist.

70. Defendant MERCK, through its affirmative misrepresentations and omissions, actively concealed from Plaintiff and his physicians the true and significant risks associated with taking FOSAMAX. The running of any applicable statute of limitations has been tolled by reason of Defendant's fraudulent concealment.

71. GENERIC DEFENDANTS, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and his physicians the true and significant risks associated with taking FOSAMAX. The running of any applicable statute of limitations has been tolled by reason of Defendants' fraudulent concealment.

72. As a result of Defendants' actions, Plaintiff and his prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this complaint, and that those risks were the direct and proximate result of Defendant's acts, omissions, and misrepresentations.

IV. COUNTS AS TO DEFENDANT MERCK

COUNT I

NEGLIGENCE

73. Plaintiff re-alleges the above paragraphs as if fully set forth herein.

74. Defendant owed Plaintiff, STANLEY EBERT, and other consumers, a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX.

75. Defendant failed to exercise due care under the circumstances and therefore breached this duty by:

- a. failing to properly and thoroughly test FOSAMAX before releasing the drug to market;
- b. failing to properly and thoroughly analyze the data resulting from the pre-marketing tests of FOSAMAX;
- c. failing to conduct sufficient post-market testing and surveillance of FOSAMAX;
- d. designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of FOSAMAX and without proper instructions to avoid the harm which could foreseeably occur as a result of using the drug;
- e. failing to exercise due care when advertising and promoting FOSAMAX; and
- f. negligently continuing to manufacture, market, advertise, and distribute FOSAMAX, including FOSAMAX sold and distributed by GENERIC DEFENDANTS, after Defendant knew or should have known of its

adverse effects.

76. As a direct and proximate consequence of MERCK's actions, omissions, and misrepresentations, Plaintiff STANLEY EBERT sustained a significant and permanent injury to his jaw. As a result, Plaintiff required and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

77. MERCK's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish MERCK and deter it from similar conduct in the future.

WHEREFORE, Plaintiff demands judgment against Defendant MERCK for any and all damages, including, but not limited to severe physical pain and suffering; mental anguish; severe anxiety; loss of life's pleasures; loss of enjoyment of life; and loss of future earning capacity, future earnings and income, past and future medical expenses, together with interest, cost of suit and counsel fees.

COUNT II

STRICT LIABILITY

78. Plaintiff re-alleges the above paragraphs as if fully set forth herein.

79. MERCK manufactured, sold, distributed, marketed, and/or supplied FOSAMAX in a defective and unreasonably dangerous condition to consumers, including Plaintiff STANLEY EBERT

80. MERCK designed, manufactured, sold, distributed, supplied, marketed, and/or promoted FOSAMAX, which was expected to reach and did in fact reach consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by MERCK.

81. Plaintiff used FOSAMAX as prescribed and in a manner normally intended, recommended, promoted, and marketed by MERCK.

82. FOSAMAX failed to perform safely when used by ordinary consumers, including Plaintiff, including when it was used as intended and in a reasonably foreseeable manner.

83. FOSAMAX was defective in its design and was unreasonably dangerous in that its unforeseeable risks exceeded the benefits associated with its design or formulation.

84. FOSAMAX was defective in design or formulation in that it posed a greater likelihood of injury than other similar medications and was more dangerous than an ordinary consumer could reasonably foresee or anticipate.

85. FOSAMAX was defective in its design and was unreasonably dangerous in that it neither bore nor was packaged with nor accompanied by warnings adequate to alert

consumers and their physicians, including Plaintiff and his physician, of the risks described herein, including, but not limited to, the risk of osteonecrosis of the jaw.

86. Although MERCK knew or should have known of the defective nature of FOSAMAX, it continued to design, manufacture, market, and sell FOSAMAX so as to maximize sales and profits at the expense of the public health and safety. By so acting, MERCK acted with conscious and deliberate disregard of the foreseeable harm caused by FOSAMAX.

87. Plaintiff could not, through the exercise of reasonable care, have discovered FOSAMAX's defects or perceived the dangers posed by the drug.

88. As a direct and proximate consequence of MERCK's conduct, Plaintiff STANLEY EBERT sustained a significant and permanent injury to his jaw. In addition, Plaintiff required and will continue to require healthcare and services as a result of his injury. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

89. Defendant MERCK's conduct as described above was committed with knowing,

conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish MERCK and deter it from similar conduct in the future.

WHEREFORE, Plaintiff demands judgment against Defendant MERCK for any and all damages, including, but not limited to severe physical pain and suffering; mental anguish; severe anxiety; loss of life's pleasures; loss of enjoyment of life; and loss of future earning capacity, future earnings and income, past and future medical expenses, together with interest, cost of suit and counsel fees.

COUNT III

BREACH OF EXPRESS WARRANTY

90. Plaintiff re-alleges the above paragraphs as if fully set forth herein.

91. Defendant MERCK expressly represented to Plaintiff STANLEY EBERT, his physician, other consumers and the medical community that FOSAMAX was safe and fit for its intended purposes, was of merchantable quality, did not produce any dangerous side effects, and had been adequately tested.

92. FOSAMAX does not conform to MERCK's express representations because it is not safe, has numerous and serious side effects, and causes severe and permanent injuries.

93. At all relevant times FOSAMAX did not perform as safely as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.

94. Plaintiff STANLEY EBERT, his physician, other consumers, and the medical community relied upon Defendant's express warranties.

95. As a direct and proximate result of Defendant's actions, Plaintiff STANLEY EBERT sustained a serious significant and permanent injury to his jaw. In addition, Plaintiff required and will continue to require healthcare and services as a result of his injury. Plaintiff has incurred and will continue to incur medical and related expenses as a result of his injury. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

96. MERCK's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish MERCK and deter it from similar conduct in the future.

WHEREFORE, Plaintiff demands judgment against Defendant MERCK for any and all damages, including, but not limited to severe physical pain and suffering; mental anguish; severe anxiety; loss of life's pleasures; loss of enjoyment of life; and loss of future earning capacity, future earnings and income, past and future medical expenses, together with interest, cost of suit and counsel fees.

COUNT IV

BREACH OF IMPLIED WARRANTY

97. Plaintiff re-alleges the above paragraphs as if fully set forth herein.

98. MERCK manufactured, distributed, advertised, promoted, and sold FOSAMAX.

99. At all relevant times, MERCK knew of the use for which FOSAMAX was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

100. MERCK was aware that consumers, including Plaintiff STANLEY EBERT, would use FOSAMAX for treatment or prevention of osteoporosis or Paget's Disease and for other off-label purposes.

101. Plaintiff, his physician and the medical community reasonably relied upon the judgment and sensibility of MERCK to manufacture and sell FOSAMAX only if it was indeed of merchantable quality and safe and fit for its intended use.

102. MERCK breached its implied warranty to consumers, including Plaintiff; FOSAMAX was not of merchantable quality or safe and fit for its intended use.

103. Consumers, including Plaintiff, his physician and the medical community, reasonably relied upon MERCK's implied warranty for FOSAMAX.

104. FOSAMAX reached consumers without substantial change in the condition in which it was manufactured and sold by MERCK.

105. As a direct and proximate result of MERCK's action, Plaintiff STANLEY EBERT sustained a significant and permanent injury to his jaw. In addition, Plaintiff required and will continue to require healthcare and services as a result of his injury.

Plaintiff has incurred and will continue to incur medical and related expenses as a result of his injury. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

106. MERCK's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish MERCK and deter it from similar conduct in the future.

WHEREFORE, Plaintiff demands judgment against Defendant MERCK for any and all damages, including, but not limited to severe physical pain and suffering; mental anguish; severe anxiety; loss of life's pleasures; loss of enjoyment of life; and loss of future earning capacity, future earnings and income, past and future medical expenses, together with interest, cost of suit and counsel fees.

COUNT V

NEGLIGENT MISREPRESENTATION

107. Plaintiff repeats, reiterates, and realleges each and every allegation contained in

this Complaint with the same force and effect as if fully set forth herein.

108. MERCK made fraudulent misrepresentations with respect to FOSAMAX in the following particulars:

a. MERCK represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that FOSAMAX had been tested and found to be safe and effective for the treatment and prevention of osteoporosis; and

b. MERCK represented that FOSAMAX was safer than other alternative medications.

109. Based on public policy, legislative enactments, and customary practices among physicians, name brand drug manufacturers, and generic drug manufacturers, Defendant Merck knew or should have known that physicians, in weighing the potential benefits and potential risks of using Alendronate and/or Fosamax and in writing prescriptions for Alendronate and/or Fosamax, would rely upon information disseminated to them by Merck, regardless of whether the prescriptions might be filled with Alendronate or Fosamax, and that many patients, in accordance with those prescriptions, would be likely to ingest Alendronate.

110. It is the public policy of the United States and of all 50 states, as reflected in the Hatch-Waxman Act and the "drug substitution laws" of all 50 states, to encourage the availability of cheaper, generic drug products that are therapeutically equivalent to name

brand products and to encourage the substitution of such generic products for name brand products in medical therapy.

111. So-called "drug substitution laws" enacted in every state authorize or require a prescription for a drug identified by product brand name or by generic name to be filled, subject to certain limited exceptions not applicable here, with a generic drug product that is therapeutically equivalent to the name brand product.

112. As a matter of industry custom and federal law, Generic Defendants simply copied verbatim, for the package inserts for Alendronate, the therapeutically relevant content of the package insert for Fosamax. Further, Generic Defendants relied upon the marketing efforts of Merck to generate sales of Alendronate.

113. Defendant Merck was aware that Generic Defendants copied verbatim, for the package inserts for Alendronate, the therapeutically relevant content of the package insert for Fosamax. Further, Merck was aware that Generic Defendants relied upon the marketing efforts of Merck to generate sales of Alendronate.

114. To obtain basic information about the properties and effects of Alendronate and/or Fosamax, physicians commonly and typically consult the information disseminated by Merck through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions and rely upon that information in forming their decisions concerning the prescribing of Alendronate and/or Fosamax to their patients.

115. Defendant Merck disseminated to physicians through package inserts, the

publication of a PDR monograph, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions, information concerning the properties and effects of Fosamax, with the intention that physicians would rely upon that information in their decisions concerning the prescription of Fosamax and/or Alendronate to their patients.

116. Plaintiff's physician prescribed, and Plaintiff ingested, Fosamax and/or Alendronate in reliance upon the information disseminated by Merck through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions.

117. Defendant Merck knew or should have known that patients, including Plaintiff, receiving prescriptions for Fosamax and/or Alendronate, written in reliance upon information Merck disseminated as the manufacturer of Fosamax, would be placed in peril of serious personal injury if the information thus disseminated and relied upon was materially inaccurate, misleading, or otherwise false.

118. Defendant Merck owed a duty to exercise reasonable care in its dissemination of information concerning Fosamax and/or Alendronate to ensure that it did not create unreasonable risk of personal injury to others, including Plaintiff.

119. Defendant Merck failed to exercise reasonable care to ensure that the information it disseminated to physicians concerning the safety information and risks of Fosamax and/or Alendronate was accurate and not misleading and disregarded its obligation to provide truthful and accurate representations regarding the safety and risk of FOSAMAX

and Alendronate to Plaintiff and her physician.

120. The representations were made by MERCK with the intent that doctors and patients, including Plaintiff and his physician rely upon them.

121. MERCK'S representations were made with the intent of defrauding and deceiving Plaintiff, other consumers, and the medical community to induce and encourage the sale of FOSAMAX.

122. Plaintiff, Plaintiff's doctors, and others relied upon the aforementioned representations.

123. MERCK'S representations evinced MERCK their callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Plaintiff.

124. As a direct and proximate result, Plaintiff developed osteonecrosis of the jaw.

125. Plaintiff required and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies and supplies and other associated costs.

126. MERCK'S conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages to the extent allowable under California law so as to punish MERCK and deter them from

similar conduct in the future.

WHEREFORE, Plaintiff demands judgment against Defendant MERCK for any and all damages, including, but not limited to severe physical pain and suffering; mental anguish; severe anxiety; loss of life's pleasures; loss of enjoyment of life; and loss of future earning capacity, future earnings and income, past and future medical expenses, together with interest, cost of suit and counsel fees.

COUNT VI

FRAUDULENT MISREPRESENTATION

127. Plaintiff re-alleges the above paragraphs as if fully set forth herein.

128. MERCK made fraudulent misrepresentations with respect to FOSAMAX in the following particulars:

a. MERCK represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that FOSAMAX had been tested and found to be safe and effective for the treatment of osteoporosis, the prevention of fractures and Paget's Disease; and

b. MERCK represented that FOSAMAX was safer and more effective than other alternative medications.

129. MERCK knew that its representations were false, yet it willfully, wantonly, and recklessly disregarded its obligation to provide truthful representations regarding the safety, efficacy and risk of FOSAMAX to consumers, including Plaintiff, and the medical

community.

130. Plaintiff's physician prescribed, and Plaintiff ingested, Fosamax and/or Alendronate in reliance upon the information disseminated by Merck through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions.

131. Defendant Merck knew or should have known that patients, including Plaintiff, receiving prescriptions for Fosamax and/or Alendronate, written in reliance upon information Merck disseminated as the manufacturer of Fosamax, would be placed in peril of serious personal injury if the information thus disseminated and relied upon was materially inaccurate, misleading, or otherwise false.

132. The representations were made by MERCK with the intent that doctors and patients, including Plaintiff, and his physician rely upon them.

133. MERCK's representations were made with the intent of defrauding and deceiving Plaintiff, other consumers, and the medical community to induce and encourage the sale of FOSAMAX.

134. Plaintiff STANLEY EBERT, Plaintiff's doctors, and others relied upon MERCK's representations.

135. MERCK's fraudulent representations evinced its callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Plaintiff.

136. As a direct and proximate result, Plaintiff STANLEY EBERT sustained a significant and permanent injury to his jaw. In addition, as a result of his injury, Plaintiff

required and will continue to require healthcare and services, and has incurred and will continue to incur medical and related expenses. Plaintiff also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

137. MERCK's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

WHEREFORE, Plaintiff demands judgment against Defendant MERCK for any and all damages, including, but not limited to severe physical pain and suffering; mental anguish; severe anxiety; loss of life's pleasures; loss of enjoyment of life; and loss of future earning capacity, future earnings and income, past and future medical expenses, together with interest, cost of suit and counsel fees.

COUNT VII

FRAUDULENT CONCEALMENT

138. Plaintiff re-alleges the above paragraphs as if fully set forth herein.

139. MERCK fraudulently concealed information with respect to FOSAMAX in the

following particulars:

- a. MERCK represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that FOSAMAX was safe and effective and fraudulently withheld and concealed information about the substantial risks of and lack of benefit from using FOSAMAX; and
- b. MERCK represented that FOSAMAX was safer and more effective than other alternative medications and fraudulently concealed information, which demonstrated that FOSAMAX was not safer or more effective than alternatives available on the market.

140. MERCK had sole access to material facts concerning the dangers and unreasonable risks associated with FOSAMAX.

141. MERCK's concealment of information about the risks associated with taking FOSAMAX and the lack of benefit derived from FOSAMAX was intentional, and MERCK knew the representations it made were false.

142. MERCK concealed information and made the misrepresentations about FOSAMAX with the intent that doctors and patients, including Plaintiff, and his physician rely upon them.

143. Plaintiff STANLEY EBERT, his physician, and others relied upon MERCK's representations and were unaware of the substantial dental and oral risks associated with taking FOSAMAX that MERCK had concealed from them.

144. As a direct and proximate result of MERCK's fraudulent concealment and misrepresentations, Plaintiff STANLEY EBERT suffered a significant and permanent injury to his jaw as well as severe and permanent injuries, including pain, mental and physical anguish and suffering, a diminished capacity for the enjoyment of life, aggravation of preexisting conditions and activation of latent conditions, and a fear of developing other harmful conditions or problems as a result of the injury. Plaintiff has suffered and will continue to suffer a loss of wages and wage-earning capacity and has incurred expenses for medical care and treatment due to the injuries caused by FOSAMAX.

145. MERCK's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish MERCK and deter it from similar conduct in the future.

WHEREFORE, Plaintiff demands judgment against Defendant MERCK for any and all damages, including, but not limited to severe physical pain and suffering; mental anguish; severe anxiety; loss of life's pleasures; loss of enjoyment of life; and loss of future earning capacity, future earnings and income, past and future medical expenses, together with interest, cost of suit and counsel fees.

COUNTS AS TO GENERIC DEFENDANTS

COUNT VIII

NEGLIGENCE

146. Plaintiff re-alleges the above paragraphs as if fully set forth herein.

147. GENERIC DEFENDANTS owed Plaintiff, STANLEY EBERT, and other consumers, a duty to exercise reasonable care when marketing, advertising, distributing, and selling ALENDRONATE.

148. GENERIC DEFENDANTS failed to exercise due care under the circumstances and therefore breached this duty by:

- a. marketing, advertising, distributing, and selling ALENRONATE to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of ALENDRONATE and without proper instructions to avoid the harm which could foreseeably occur as a result of using the drug;
- b. negligently continuing to market, distribute and sell ALENDRONATE after GENERIC DEFENDANTS knew or should have known of its adverse effects.

149. As a direct and proximate consequence of GENERIC DEFENDANTS' actions or omissions, Plaintiff STANLEY EBERT sustained a significant and permanent injury to his jaw. As a result, Plaintiff required and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of

preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

WHEREFORE, Plaintiff demands judgment against GENERIC DEFENDANTS for any and all damages, including, but not limited to severe physical pain and suffering; mental anguish; severe anxiety; loss of life's pleasures; loss of enjoyment of life; and loss of future earning capacity, future earnings and income, past and future medical expenses, together with interest, cost of suit and counsel fees.

COUNT IX

STRICT LIABILITY

150. Plaintiff re-alleges the above paragraphs as if fully set forth herein.

151. GENERIC DEFENDANTS sold, distributed, marketed, and/or supplied ALENDRONATE in a defective and unreasonably dangerous condition to consumers, including Plaintiff STANLEY EBERT

152. GENERIC DEFENDANTS sold, distributed, supplied, marketed, and/or promoted ALENDRONATE, which was expected to reach and did in fact reach consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by GENERIC DEFENDANTS.

153. Plaintiff used ALENDRONATE as prescribed and in a manner normally

intended, recommended, promoted, and marketed by Defendant.

154. ALENDRONATE failed to perform safely when used by ordinary consumers, including Plaintiff, including when it was used as intended and in a reasonably foreseeable manner.

155. ALENDRONATE was defective in its design and was unreasonably dangerous in that its unforeseeable risks exceeded the benefits associated with its design or formulation.

156. ALENDRONATE was defective in design or formulation in that it posed a greater likelihood of injury than other similar medications and was more dangerous than an ordinary consumer could reasonably foresee or anticipate.

157. ALENDRONATE was defective in its design and was unreasonably dangerous in that it neither bore nor was packaged with nor accompanied by warnings adequate to alert consumers or their physicians, including Plaintiff and his physician, of the risks described herein, including, but not limited to, the risk of osteonecrosis of the jaw.

158. Plaintiff could not, through the exercise of reasonable care, have discovered ALENDRONATE's defects or perceived the dangers posed by the drug.

159. As a direct and proximate consequence of GENERIC DEFENDANTS' conduct, Plaintiff STANLEY EBERT sustained significant and permanent injury to his jaw. In addition, Plaintiff required and will continue to require healthcare as a result of his injury. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of

life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

WHEREFORE, Plaintiff demands judgment against GENERIC DEFENDANTS for any and all damages, including, but not limited to severe physical pain and suffering; mental anguish; severe anxiety; loss of life's pleasures; loss of enjoyment of life; and loss of future earning capacity, future earnings and income, past and future medical expenses, together with interest, cost of suit and counsel fees.

COUNT X

BREACH OF EXPRESS WARRANTY

160. Plaintiff re-alleges the above paragraphs as if fully set forth herein.

161. GENERIC DEFENDANTS expressly represented to Plaintiff STANLEY EBERT, his physician, other consumers and the medical community that ALENDRONATE was safe and fit for its intended purposes, was of merchantable quality, did not produce any dangerous side effects, and had been adequately tested.

162. ALENDRONATE does not conform to GENERIC DEFENDANTS' express representations because it is not safe, has numerous and serious side effects, and causes severe and permanent injuries.

163. At all relevant times ALENDRONATE did not perform as safely as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.

164. Plaintiff STANLEY EBERT, his physician, other consumers, and the medical community relied upon Defendant's express warranties.

165. As a direct and proximate result of Defendant's actions, Plaintiff STANLEY EBERT sustained a serious significant and permanent injury to his jaw. In addition, Plaintiff required and will continue to require healthcare and services as a result of his injury. Plaintiff has incurred and will continue to incur medical and related expenses as a result of his injury. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

166. GENERIC DEFENDANTS' conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish GENERIC DEFENDANTS and deter it from similar conduct in the future.

WHEREFORE, Plaintiff demands judgment against GENERIC DEFENDANTS

for any and all damages, including, but not limited to severe physical pain and suffering; mental anguish; severe anxiety; loss of life's pleasures; loss of enjoyment of life; and loss of future earning capacity, future earnings and income, past and future medical expenses, together with interest, cost of suit and counsel fees.

COUNT XI

BREACH OF IMPLIED WARRANTY

167. Plaintiff re-alleges the above paragraphs as if fully set forth herein.

168. GENERIC DEFENDANTS manufactured, distributed, advertised, promoted, and sold ALENDRONATE.

169. At all relevant times, GENERIC DEFENDANTS knew of the use for which ALENDRONATE was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

170. GENERIC DEFENDANTS was aware that consumers, including Plaintiff STANLEY EBERT, would use ALENDRONATE for treatment or prevention of osteoporosis or Paget's Disease and for other off-label purposes.

171. Plaintiff, his physician and the medical community reasonably relied upon the judgment and sensibility of GENERIC DEFENDANTS to manufacture and sell ALENDRONATE only if it was indeed of merchantable quality and safe and fit for its intended use.

172. GENERIC DEFENDANTS breached its implied warranty to consumers, including Plaintiff; ALENDRONATE was not of merchantable quality or safe and fit for

its intended use.

173. Consumers, including Plaintiff, his physician and the medical community, reasonably relied upon GENERIC DEFENDANTS' implied warranty for ALENDRONATE.

174. ALENDRONATE reached consumers without substantial change in the condition in which it was manufactured and sold by GENERIC DEFENDANTS.

175. As a direct and proximate result of GENERIC DEFENDANTS' action, Plaintiff STANLEY EBERT sustained a significant and permanent injury to his jaw. In addition, Plaintiff required and will continue to require healthcare and services as a result of his injury. Plaintiff has incurred and will continue to incur medical and related expenses as a result of his injury. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

176. GENERIC DEFENDANTS' conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish GENERIC DEFENDANTS and deter it from similar

conduct in the future.

WHEREFORE, Plaintiff demands judgment against GENERIC DEFENDANTS for any and all damages, including, but not limited to severe physical pain and suffering; mental anguish; severe anxiety; loss of life's pleasures; loss of enjoyment of life; and loss of future earning capacity, future earnings and income, past and future medical expenses, together with interest, cost of suit and counsel fees.

COUNT XII

FRAUDULENT MISREPRESENTATION

177. Plaintiff re-alleges the above paragraphs as if fully set forth herein.

178. GENERIC DEFENDANTS made fraudulent misrepresentations with respect to ALENDRONATE in the following particulars:

- a. GENERIC DEFENDANTS represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that ALENDRONATE had been tested and found to be safe and effective for the treatment of osteoporosis, the prevention of fractures and Paget's Disease; and
- b. GENERIC DEFENDANTS represented that ALENDRONATE was safer and more effective than other alternative medications.

179. GENERIC DEFENDANTS knew that its representations were false, yet it willfully, wantonly, and recklessly disregarded its obligation to provide truthful

representations regarding the safety, efficacy and risk of ALENDRONATE to consumers, including Plaintiff, and the medical community.

180. The representations were made by GENERIC DEFENDANTS with the intent that doctors and patients, including Plaintiff, and his physician rely upon them.

181. GENERIC DEFENDANTS' representations were made with the intent of defrauding and deceiving Plaintiff, other consumers, and the medical community to induce and encourage the sale of ALENDRONATE.

182. Plaintiff STANLEY EBERT, Plaintiff's doctors, and others relied upon GENERIC DEFENDANTS' representations.

183. GENERIC DEFENDANTS' fraudulent representations evinced its callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Plaintiff.

184. As a direct and proximate result, Plaintiff STANLEY EBERT sustained a significant and permanent injury to his jaw. In addition, as a result of his injury, Plaintiff required and will continue to require healthcare and services, and has incurred and will continue to incur medical and related expenses. Plaintiff also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain

and suffering and loss of wages and wage-earning capacity.

185. GENERIC DEFENDANTS' conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

WHEREFORE, Plaintiff demands judgment against GENERIC DEFENDANTS for any and all damages, including, but not limited to severe physical pain and suffering; mental anguish; severe anxiety; loss of life's pleasures; loss of enjoyment of life; and loss of future earning capacity, future earnings and income, past and future medical expenses, together with interest, cost of suit and counsel fees.

COUNT XIII

NEGLIGENT MISREPRESENTATION

186. Plaintiff repeats, reiterates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

187. GENERIC DEFENDANTS made fraudulent misrepresentations with respect to ALENDRONATE in the following particulars:

- a. GENERIC DEFENDANTS represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory

submissions that ALENDRONATE had been tested and found to be safe and effective for the treatment and prevention of osteoporosis; and

- b. GENERIC DEFENDANTS represented that ALENDRONATE was safer than other alternative medications.

188. GENERIC DEFENDANTS knew that their representations were false, yet they willfully, wantonly, and recklessly disregarded their obligation to provide truthful representations regarding the safety and risk of ALENDRONATE to consumers, including Plaintiff, and the medical community.

189. The representations were made by GENERIC DEFENDANTS with the intent that doctors and patients, including Plaintiff and his physician rely upon them.

190. GENERIC DEFENDANTS' representations were made with the intent of defrauding and deceiving Plaintiff, other consumers, and the medical community to induce and encourage the sale of ALENDRONATE.

191. Plaintiff, Plaintiff's doctors, and others relied upon the aforementioned representations.

192. GENERIC DEFENDANTS' fraudulent representations evinced GENERIC DEFENDANTS their callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Plaintiff.

193. As a direct and proximate result, Plaintiff developed osteonecrosis of the jaw.

194. Plaintiff required and will continue to require healthcare and services. Plaintiff

has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies and other associated costs.

195. GENERIC DEFENDANTS' conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages to the extent allowable under California law so as to punish GENERIC DEFENDANTS and deter them from similar conduct in the future.

WHEREFORE, Plaintiff demands judgment against GENERIC DEFENDANTS for any and all damages, including, but not limited to severe physical pain and suffering; mental anguish; severe anxiety; loss of life's pleasures; loss of enjoyment of life; and loss of future earning capacity, future earnings and income, past and future medical expenses, together with interest, cost of suit and counsel fees.

COUNT XIV

FRAUDULENT CONCEALMENT

196. Plaintiff re-alleges the above paragraphs as if fully set forth herein.

197. GENERIC DEFENDANTS fraudulently concealed information with respect to ALENDRONATE in the following particulars:

- a. GENERIC DEFENDANTS represented through its labeling,

advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that ALENDRONATE was safe and effective and fraudulently withheld and concealed information about the substantial risks of and lack of benefit from using ALENDRONATE; and

b. GENERIC DEFENDANTS represented that ALENDRONATE was safer and more effective than other alternative medications and fraudulently concealed information, which demonstrated that ALENDRONATE was not safer or more effective than alternatives available on the market.

198. GENERIC DEFENDANTS had sole access to material facts concerning the dangers and unreasonable risks associated with ALENDRONATE.

199. GENERIC DEFENDANTS' concealment of information about the risks associated with taking ALENDRONATE and the lack of benefit derived from ALENDRONATE was intentional, and GENERIC DEFENDANTS knew the representations it made were false.

200. GENERIC DEFENDANTS concealed information and made the misrepresentations about ALENDRONATE with the intent that doctors and patients, including Plaintiff, and his physician rely upon them.

201. Plaintiff STANLEY EBERT, his physician, and others relied upon GENERIC DEFENDANTS' representations and were unaware of the substantial dental and oral

risks associated with taking ALENDRONATE that GENERIC DEFENDANTS had concealed from them.

202. As a direct and proximate result of GENERIC DEFENDANTS' fraudulent concealment and misrepresentations, Plaintiff STANLEY EBERT suffered a significant and permanent injury to his jaw as well as severe and permanent injuries, including pain, mental and physical anguish and suffering, a diminished capacity for the enjoyment of life, aggravation of preexisting conditions and activation of latent conditions, and a fear of developing other harmful conditions or problems as a result of the injury. Plaintiff has suffered and will continue to suffer a loss of wages and wage-earning capacity and has incurred expenses for medical care and treatment due to the injuries caused by ALENDRONATE.

203. GENERIC DEFENDANTS' conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish GENERIC DEFENDANTS and deter it from similar conduct in the future.

WHEREFORE, Plaintiff demands judgment against GENERIC DEFENDANTS for any and all damages, including, but not limited to severe physical pain and suffering; mental anguish; severe anxiety; loss of life's pleasures; loss of enjoyment of life; and loss of future earning capacity, future earnings and income, past and future medical expenses, together with interest, cost of suit and counsel fees.

GLOBAL PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants MERCK and
GENERIC DEFENDANTS, as follows:

- a. compensatory damages on each cause of action;
- b. punitive damages on each cause of action;
- c. reasonable attorneys' fees where recoverable;
- d. costs of this action; and
- e. such other additional and further relief as the Court may deem necessary,
appropriate, and just.

V. DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all counts and issues so triable.



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